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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,521

09/23/2003

Hugh Trout III

1449

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HUGH H. TROUT, III, MD
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SUITE 204
BETHESDA, MD 20814

EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

09/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/667,521

Applicant(s)

TROUT ET AL.

Examiner

Melanie Tyson

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3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-9 and 12-24 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9 and 12-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 June 2008 has been entered. Claims 3, 10, and 11 have been cancelled and claims 22-24 remain withdrawn from consideration.

Drawings

The drawings are objected to because Figure 2A contradicts Figures 1A and 1B. Figures 1A and 1B illustrate a separate occlusive device (50) and fastener (30). Figure 2A labels the fastener (30) as the combination of the tip (40) and occlusive member (50). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 4, 5, 12, 13, 15-18, 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Ho et al. (2001/0047181 A1). Ho discloses an occlusive system for use at a surgical site (see entire document) comprising a fastener (134) in that it assists in compressing the surgical component (for example, graft vessel 12) to a vessel wall (for example, see Figure 2C), thus is considered a "fastener" that is capable of attaching a surgical component to a vessel wall, an occlusive device in the form of a coil (126) disposed adjacent to the fastener (around its outer surface, or considered adjacent the fastener tip 136) that is capable of occluding blood through a vessel (for example, see Figure 2C, wherein the coils sufficiently occludes the opening in vessel 14), and a penetration apparatus (the combination of elements 102, 104, and 108) in communication with the fastener and fastener tip (for example, see Figure 1C), wherein the occlusive device has a substantially open configuration (for example, see Figure 1A)

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and collapses, or evolves, into a substantially closed configuration (for example, see Figures 2C). The occlusive device is maintained substantially in the open position by the presence of the penetration apparatus in that the occlusive device remains open until it is released from the penetration member at which time it collapses, or evolves, into a substantially closed position.

It is noted that the applicant has not invoked 112 6th paragraph in claim 21, since the terms "fastener" and "occlusive" are considered to impart structure, thus modify the phrase "means for" with sufficient structure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-9, 14, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ho et al.

Regarding claims 6-9, Ho discloses the claimed invention except that the occlusive device comprises a band, a ribbon, a valve, or a flap. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide the system with an occlusive device in the form of a band, a ribbon, a valve, or a flap, since the applicant has not disclosed that an occlusive device in the form of a band, ribbon, valve, provides an advantage, is used for a particular purpose, or solves a stated problem over an occlusive device in the form of a coil. It appears the prior art occlusive device would perform equally well especially since the applicant indicates as such in the disclosure (i.e., the occlusive member may comprise a coil, band, ribbon, flap, or valve; for example, see paragraph 39).

Regarding claim 14, Ho discloses the claimed invention except that the occlusive device is disposed within the fastener. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to dispose the occlusive member within the fastener, as opposed to adjacent to the fastener, since the applicant has not disclosed that such a configuration provides an advantage, is used for a particular purpose, or solves a stated problem. It appears the prior art occlusive member located adjacent to the fastener would perform equally well especially since the applicant indicates as such in the disclosure (i.e., the occlusive device 50 may be disposed within and/or located adjacent to the fastener; for example, see paragraph 41).

Regarding claims 19 and 20, Ho discloses a fastener means and occlusive means as claimed (see rejection above for detailed description of the same elements). Ho fails to disclose the penetration apparatus is in reversible communication with the

fastener and the occlusive device. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to do so, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. Furthermore, it appears the prior art irreversible penetration apparatus would perform equally well especially since the applicant indicates as such in the disclosure (i.e., fastener 30 is reversibly or irreversibly secured to tip 40; for example, see paragraph 46).

Response to Arguments

Applicant's arguments filed 30 June 2008 have been fully considered but they are not persuasive.

Regarding the drawings, the applicant states that occlusive device 50, fastener 30, and tip 40 are separate elements that may be used in multiple combinations. It is the examiner's position that this is exactly the basis for the objection. The figures are objected to because Figure 2A labels the combination of the occlusive device 50 and tip 40 as the fastener 30, when in fact all three components are separate elements. Therefore, the objection stands.

Regarding the claims, the applicant argues primarily that the prior art fails to disclose each and every element as recited. Examiner respectfully disagrees. The applicant argues that Ho fails to disclose a fastener capable of attaching a surgical component to a vessel wall. However, it is the examiner's position that Ho discloses a fastener 134 as claimed in that it assists in compressing the surgical component 12 to a

vessel wall (for example, see Figure 2C), thus is considered a "fastener" that is capable of attaching a surgical component to a vessel wall.

Applicant further argues that bands, ribbons, valves, and flaps are not well known in the art. The examiner has provided references to show that these devices are well known in the surgical art (7,087,066 B2 - band 194; 2002/0128671 A1 - combination of coil and ribbon; 6,221,091 B1 - flap valve). Modifying Ho's occlusive device with devices well known art would have been obvious to a person of ordinary skill in the art at the time the invention was made, since the applicant has not disclosed that an occlusive device in the form of a band, ribbon, or valve, provides an advantage, is used for a particular purpose, or solves a stated problem over a coil. It appears the prior art occlusive device would perform equally well especially since the applicant indicates as such in the disclosure (i.e., the occlusive member may comprise a coil, band, ribbon, flap, or valve; for example, see paragraph 39).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
September 10, 2008

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773